DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 11-909/S-030

Pfizer Inc.
Attention: Denise Andrews
Regulatory Affairs
235 E 42nd Street
New York, NY 10017

Dear Ms. Andrews:

We acknowledge receipt of your supplemental new drug application dated October 17, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nardil (phenelzine sulfate) 15 mg Tablets.

This supplemental application provides for the addition of the Pfizer Inc. name to reflect that Pfizer Inc. has acquired the Warner-Lambert/Parke-Davis Company.

We have completed the review of this supplemental application, S-030, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted October 17, 2001/Label Code 0270G081Q), which incorporates all of the revisions listed above. Accordingly, this supplemental application is approved effective on the date of this letter.

Labeling changes of the kind which you have proposed are permitted by section 314.70(c) of the regulations to be instituted prior to approval of the supplement. It is understood that the changes, described in the above NDA supplements, have been made.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Mr. Paul David, R.Ph., Senior Regulatory Project Manager, at (301) 594-5530.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Russell Katz

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